



0.4 mL MINI SPORE AMPULES For Monitoring Steam

Crosstex Code: OS1-50-06

Product Description

0.4 mL Mini Spore Ampules are Self-Contained Biological Indicators for monitoring Steam processes. Each kit consists of:

- Mini Spore Ampules which contain modified Trypticase[®] Soy Broth (TSB) with a pH indicator and *Geobacillus stearothermophilus* (Cell Line 7953). The modified TSB will transition from the initial purple color to yellow and/or demonstrate turbidity in the presence of bacterial growth.
- Negative Control Ampules which contain modified TSB with a pH indicator and a single glass bead to allow for clear segregation from the Spore Ampules.

Intended Use

The Mini Spore Ampules may be utilized to monitor Steam sterilization efficacy. The ampules are ideal for monitoring liquid steam sterilization cycles but may also be utilized in monitoring dry loads. Mini Spore Ampules are labeled For Industrial Use Only.

Instructions for Use

Exposure: Mini Spore Ampules may be placed inside representative materials (containers of liquid) or within the chamber directly. Package or wrap product as usual, if applicable. Locate product ampules in most difficult location to sterilize, as outlined in your specific sterilization validation protocol or according to standard operating procedure. Run the cycle.

After sterilization or exposure, remove ampules or product from sterilizer. Allow product or ampules to cool to the touch. No activation is required.



Handle Mini Spore Ampules with care as contents are extremely hot. Leaving the Mini Spore Ampules in the sterilizer post-exposure may have a negative impact on the product's performance. As such, Mini Spore Ampules left in the chamber for extended periods of time (>24 hours) post-exposure should be discarded.

Incubation: Place the processed Mini Spore Ampules, one Negative Control Ampule and one Positive Control (unprocessed Mini Spore Ampule) in a vertical position in an incubator at 59°C to 63°C for a minimum of 48 hours.

Monitoring: Examine the ampules daily during incubation. Record observations. All positive ampules should be disposed of immediately.

For unexpected positives, it is recommended that a Gram stain be performed. Gram positive rods are characteristic of the indicator organism.



Interpretation: Negative Control: The Negative Control Ampule should not exhibit a color change to yellow and/or demonstrate turbidity. Utilize the Negative Control as a color comparison for the exposed Mini Spore Ampules, where applicable.

Positive Control Mini Spore Ampule: The Positive Control Ampule should exhibit a color change to yellow and/or demonstrate turbidity. Utilize the Positive Control as a color comparison for the exposed ampules, where applicable. If the Positive Control does not demonstrate a yellow color and/or turbidity, the results for the Test Mini Spore Ampules should not be considered valid. Verify incubation conditions were met.

Test Mini Spore Ampules: A passing sterilization cycle is indicated by a test ampule which remains purple in color and is free from turbidity. A failed sterilization cycle is indicated by turbidity and/or a color change to yellow.

Physical Properties

Process	Steam
Dimensions	Approximately 32 mm x 6.4 mm
Packaging	Mini Spore Ampules : 50/Kit Negative Control Ampules: 5/Kit
Volume	0.4 mL

Monitoring Frequency

For greatest control of sterilized goods, it is recommended that one or more Mini Spore Ampules be included with every load.

Performance Characteristics

Population	1.0 to 5.0 x 10 ⁶ per ampule
Purity	No evidence of contamination present in sufficient numbers to adversely affect the finished product.
Steam Resistance	<p><i>D</i> value at 121°C ± 0.5°C 1.5 to 3.0 minutes</p> <p>The Steam <i>D</i> value range is based on the requirements outlined in the USP, ISO 11138-3 and guidance issued by the Food & Drug Administration (FDA).</p> <p>Survival – Kill Times Calculated based on the formulas outlined in the USP, ISO 11138-1 and guidance issued by the FDA.</p> <p><i>z</i> value ≥6°C</p> <p>The <i>z</i> value is based on <i>D</i> values at three temperatures in the range of 110°C to 130°C. Crosstex typically utilizes <i>D</i> values determined at 118°C, 121°C and 126°C.</p>
Post-Market Criteria	<p>Population: 50% to 300% of certified population</p> <p><i>D</i> value: ± 20% of the certified <i>D</i> value</p> <p>Survival Time: All Mini Spore Ampules result in growth at the certified survival time</p> <p>Kill Time: All Mini Spore Ampules result in no growth at the certified kill time</p>

Compliance

ISO 11138-1 Sterilization of health care products – Biological indicators – Part 1: General requirements

ISO 11138-3 Sterilization of health care products – Biological indicators – Part 3: Biological indicators for moist heat sterilization processes

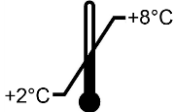




USP <55> Biological Indicators – Resistance Performance Tests

USP Biological/Official Monographs

USP Biological Indicator for Steam Sterilization, Self-Contained

Crosstex has a validated method for Total Viable Spore Count. Please inquire for the Technical Bulletin entitled *Population Verification of 0.4 mL Mini Spore Ampules* to ensure consistent methodologies are being utilized when performing verification testing.

Storage and Shelf Life

	Refrigerate at 2°C to 8°C		Keep away from sunlight
	Do not freeze		Protect from heat, radioactive sources, & sterilizing agents
<p>Shelf Life</p>	24 Months from the date of manufacture		
	Do not use damaged Mini Spore Ampules or Mini Spore Ampules which demonstrate turbidity or have transitioned to a yellow color. Do not use after expiration date. The Mini Spore Ampules contain live cultures and should be handled with care.		

Disposal

Autoclave for not less than 30 minutes at 121°C or per validated disposal cycle prior to discard.

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